

REMARKS

Introduction

This response is supplemental to Applicants' response filed June 24, 2009 and substitute response filed on July 17, 2009. Please enter the response filed July 17, 2009 and then enter the instantly submitted amendments in addition thereto.

In this response, claims 63, 110 and 111 as helpfully suggested by the Examiner during an in-person interview held on July 20, 2009. Namely, the lysing now "comprises" the listed actions, while the lysing reagent is recited as consisting of a detergent, optionally water, optionally a buffer, and optionally a chelating agent. Claims 69, 71 and 72 are also amended to delete reference to "at least one." Claims 63, 66-93 and 101-111 remain currently pending in the present application. No new matter has been added.

Also submitted herewith is a Declaration of Dr. Dirk Loeffert.

Applicants respectfully request favorable consideration of the instant application in view of the present amendments, the instantly submitted Declaration of Dr. Loeffert and the foregoing remarks.

The Interview

Applicants gratefully acknowledge the courtesies extended to their representatives during a personal interview on July 20, 2009. The content of the interview is accurately reflected on the Interview Summary Record.

New Amendments and Declaration of Dr. Loeffert

Applicants respectfully submit that in view of the instant amendments and statements provided by Dr. Loeffert submitted herewith, this application is in condition for allowance. That is, during the Interview, the Examiner suggested that it was her position that the combination of the references being relied upon rendered the instantly claimed invention obvious. The Examiner admits that Deggerdal does not teach or suggest contacting biological material that contains DNA with a solid support having dried thereon the claimed lysing reagent and a RNA digesting enzyme. However, the Examiner further takes the position that one or more of Shieh, Harvey and/or Rudi provide for the deficiencies of Deggerdal. Applicants respectfully disagree.

To wit, Dr. Loeffert has provided a clear indication that one of skill in the art would not have believed such a combination to have worked for at least the following reasons.

In his Declaration, Dr. Loeffert states, at ¶¶3-5 that as one of ordinary skill in the art, he would not have expected lysis of a biological material that contains DNA with a solid support having dried thereon, a lysing reagent and a RNA digesting enzyme, wherein the lysing reagent includes only a detergent, optionally water, optionally a buffer and optionally a chelating agent to have worked. Indeed, Dr. Loeffert recalls that when he first heard of this type of assay, he did not think such an assay would work. Therefore, as one of skill in the art, to him it was completely unexpected that when a lysing reagent and an RNA digesting enzyme are dried on a support, the resultant could even be used to accomplish lysis while maintaining the RNase enzyme activity. Thus, since one of skill did not think the method of claim 1 would work, there is no *prima facie* obviousness case made out by the references being relied upon. Indeed, what Dr. Loeffert's declaration provides is evidence that one of skill in the art would not have sought to have combined the combination of teachings being relied upon. One of skill in the art simply would not have dried the lysing agent being claimed with an RNA digesting enzyme on a support and seek to use that material for conducting lysis.

Dr. Loeffert further states that it is well known in the art that detergents like SDS efficiently denature proteins and thus destroy an enzyme capability to perform its function. It was even more unexpected to Dr. Loeffert that indeed the process works much faster and more efficiently than other methods for lysis of biological samples. Based his knowledge of literature such as, A Laboratory Guide to RNA, by Paul A. Krieg, copyright 1996, and which was available before the priority of the instant application, Dr. Loeffert avers at ¶4 and 5,

"it was certainly thought in the art in 1999 that a detergent would inhibit RNase (i.e. an RNA digesting enzyme). See, i.e. p. 76 of Dr. Krieg's book where it is stated at (i) that "SDS is an efficient anti-RNase detergent." This was my opinion as well since I believed that detergents would routinely inhibit enzymes such as RNA digestion enzymes. As one of skill in the art in 1999, I would have believed that a detergent could inactivate the RNA digesting enzyme. But surprisingly and unexpectedly by having both of these agents dried on the support together, their activity can be

maintained over long term storage, and yet even more surprisingly, they are both immediately available and active upon contact of the biological sample when it is added to the support.

The fact products of the present application have at least similar or even superior properties to products where a lysing reagent and RNA digesting enzyme are not dried on a support, was surprising and unexpected to me, especially in view of literature such as Dr. Krieg's handbook. The fact that the specific lysing reagent (including detergent, optionally water, optionally chelating agent, optionally buffer) and an RNA digesting enzyme are dried on the support ahead of time is critical to the unexpected results. Moreover, I expect that lysis using such a support with lysing reagent and RNA digesting enzyme to work across all embodiments of the '636 application."

It is respectfully submitted that the instantly submitted Declaration of Dr. Loeffert taken together with the instant claim amendments renders this case allowable. Namely, it is respectfully submitted that none of the cited references teach or suggest all of the elements of the claims, alone or in any combination. Accordingly, applicants request withdrawal all remaining grounds of rejection.

Conclusion

Applicants believe that the claims are in condition for allowance and respectfully request such allowance. The Examiner is invited and encouraged to contact the undersigned at 202-508-3400 to discuss any matter in this application. Although it is believed that no fees beyond the fees for a three month extension of time are required for the filing of this paper, if any additional fees are required, they may be charged to Deposit Account No. 50-4254, referencing Attorney Docket No. 2902162-015000.

Respectfully submitted,

BAKER, DONELSON, BEARMAN, CALDWELL &
BERKOWITZ, P.C.

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